Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of The Effect of Melatonin on Treatment of Pediatric Refractory and Super-Refractory Generalized Convulsive Status Epilepticus in 1 to 15 years old Children

Protocol summary

Study aim
Determining the effect of melatonin in the treatment of refractory and super-refractory generalized convulsive status epilepticus and the factors affecting it in children aged 1 to 15 years old.

Design
randomized controlled clinical trial (pilot study), parallel group, single blind, 40 participants.

Settings and conduct
This study will be conducted in the Shiraz Namazi Hospital PICU. According to the group they are placed in, the patients will or will not receive melatonin in addition to the standard treatment, and their condition will be evaluated by the pediatric ICU fellowship physician. The study is single blinded (Children and their legal guardian are not informed about the allocation of melatonin)

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children aged 1 to 15 years old admitted to Shiraz Namazi Hospital PICU with the diagnosis of refractory and super-refractory generalized convulsive status epilepticus Exclusion criteria: dissent of patient's legal guardian regarding administration of melatonin, inability to use NG tube for any reason, occurrence of adverse drug reaction to melatonin

Intervention groups
The intervention group consists of patients with refractory and super-refractory status epilepticus who will receive standard treatment including two lines of antiseizure drugs and then melatonin at the same time as anesthetic drugs. The comparison group consists of patients with refractory and super-refractory status epilepticus who will receive standard treatment including two lines of antiseizure drugs and then anesthetic drugs.

Main outcome variables
seizure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181014041338N2**
Registration date: **2023-01-22, 1401/11/02**
Registration timing: **prospective**

Last update: **2023-01-22, 1401/11/02**
Update count: **0**

Registration date
2023-01-22, 1401/11/02

Registrant information
Name
Hamid Nemati
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3623 4508
Email address
meshham5@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-01, 1401/11/12

Expected recruitment end date
2023-08-01, 1402/05/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of The Effect of Melatonin on Treatment of Pediatric Refractory and Super-Refractory Generalized Convulsive Status Epilepticus in 1 to 15 years old Children

Public title
Effect of Melatonin in treatment of Pediatric Status Epilepticus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
1 to 15 years old children admitted in Namazi hospital PICU diagnosed with refractory and super-refractory generalized convulsive status epilepticus

Exclusion criteria:
Dissent of patient's legal guardian regarding administration of melatonin. Inability to use NG tube for any reason. Occurrence of adverse drug reaction to melatonin.

Age
From **1 year** old to **15 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomize the allocation of melatonin to patients, block randomization method (two blocks of 20, one for receiving melatonin and one for not receiving melatonin) is used, the unit of which is individual. To achieve this goal, web-based randomization (www.randomization.com website) is used to randomly determine how 40 patients are placed in two groups of 20 (randomly placing numbers 1 to 40 in two groups of 20)

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, single blinding is used and only participants (patients and their legal guardians) have been kept blind. Since the patients are minors and the informed consent for participating in the study is obtained from their parents/guardians, the parent/guardian will also be blinded to receiving or not receiving melatonin. The other people involved in the study are all aware of the allocation or non-allocation of melatonin to patients. Since this is a pilot study and melatonin will be used after two antiseizure drugs and simultaneously with anesthetic drugs and in patients with decreased level of consciousness (through nasogastric tube), placebo will not be used in the control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of shiraz University of Medical Sciences

Street address
Zand St., Shiraz, Iran

City
shiraz

Province
Fars

Postal code
71348-14336

Approval date
2022-06-14, 1401/03/24

Ethics committee reference number
IR.SUMS.MED.REC.1401.149

Health conditions studied

1

Description of health condition studied
Pediatric status epilepticus

ICD-10 code
G40.411

ICD-10 code description
Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus

Primary outcomes

1

Description
Cessation of generalized convulsive status epilepticus

Timepoint
Continuous 24-hour monitoring from the moment the patient enters the pediatric intensive care unit

Method of measurement
Clinical observation by PICU's attending physician and staff

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:
Category
Treatment - Drugs

2

Description
Control group:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Meshkat Nemati
Street address
Namazi Sq, shiraz, fars.
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nemazee_inf@sums.ac.ir
Web page address
https://namazi.sums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab Memarpour
Street address
Namazi Hospital, Namazi sq, Shiraz, Fars,
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nematih@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Nemati
Position
Assistant professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available